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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,650	11/28/2000	William D. Huse	--06271.0024.DVUS01	5769

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09/10/2003

Patent Administrator  
KATTEN MUCHIN ZAVIS ROSEMAN  
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EXAMINER

KETTER, JAMES S

ART UNIT

PAPER NUMBER

1636

22

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER
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22

DATE MAILED:

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner for Patents**

--See attached--

**Office Action Summary**

Application No.

09/726,650

Applicant(s)

HUSE ET AL.

Examiner

James S. Ketter

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>19</u> . | 6) <input type="checkbox"/> Other: _____                                    |

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 22-29 stand rejected under 35 U.S.C. 102(e) as being anticipated by Iverson et al. (A'), for reasons of record set forth in Paper No. 19, mailed 14 March 2003.

Applicants argue, at page 5 of the response filed 13 June 2003, that the reference fails to teach each and every limitation of the claimed invention, pointing out that the antibodies of the reference were made using the hybridoma approach. However, it is clear that a product-by-process is still a product, and if there is no aspect of the recited process which would confer a patentable distinction upon said product, then the prior art product would anticipate the claimed product. Applicant has not shown how the process recitation in the claimed invention would lead to a structural difference over the antibodies of the reference.

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Claims 22-29 stand rejected under 35 U.S.C. 102(e) as being anticipated by Schochetman et al. (B), for reasons of record set forth in Paper No. 19, mailed 14 March 2003.

Applicants argue, at page 6 of the response filed 13 June 2003, that the reference fails to teach each and every limitation of the claimed invention, pointing out that the antibodies of the reference were made using the hybridoma approach. However, it is clear that a product-by-process is still a product, and if there is no aspect of the recited process which would confer a patentable distinction upon said product, then the prior art product would anticipate the claimed product. Applicant has not shown how the process recitation in the claimed invention would lead to a structural difference over the antibodies of the reference.

Claims 22-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Kim et al. (C), for reasons of record set forth in Paper No. 19, mailed 14 March 2003.

Applicants argue, at page 6 of the response filed 13 June 2003, that the reference fails to teach each and every limitation of the claimed invention, pointing out that the antibodies of the reference were made using an immunization approach. However, it is clear that a product-by-process is still a product, and if there is no aspect of the recited process which would confer a patentable distinction upon said product, then the prior art product would anticipate the claimed product. Applicant has not shown how the process recitation in the claimed invention would lead to a structural difference over the antibodies of the reference.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in Paper No. 13, mailed 17 June 2002, and Paper No. 19, mailed 14 March 2003.

At page 7, second paragraph, Applicants argue that it is common practice to generate an antibody without knowing its structure a priori. However, this is an argument which goes to enablement, not written description. Furthermore, if one does not know the structure of a chemical entity, then one does not have possession of it. The mere knowledge of function does not confer knowledge of structure, as there may be a vast number of structures quite distinct from one another sharing the same function. Applicants then set forth three points. First it is argued that a priori knowledge of the structure of the antibody is not required to practice the instant invention. However, this goes to enablement, specifically in the “how to make” aspect. Second, Applicants argue that catalytic antibodies are a species of the genus of antibodies. However, catalytic antibodies form a group that, while being narrower than the group of all antibodies, represents a very large genus unto itself. Third, Applicants argue that the catalytic antibodies claimed are defined by their “selective and specific binding to targets” selected by the practitioner. However, mere function cannot serve to show possession of an invention in a large genus in the absence of knowledge by the practitioner of structure-function correlation.

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At the third paragraph at page 7, Applicants argue that antibodies pulled out of a library had the predicted catalytic activities. However, this argument goes to enablement, particularly to the “how to make aspect”. Applicants have not shown that, given the proposed catalytic function, structures of the catalytic antibodies were known before the screening was performed.

At the paragraph bridging pages 7 and 8, Applicant argues that “the method of the present invention eliminates any need for the kind of structure-function information discussed by the Examiner...” However, the instant claims are drawn to products, not methods.

At the first full paragraph at page 8, Applicants argue that a number of patents have issued to antibodies without description of structural features of those antibodies. First, however, it must be noted that each application is examined on its own merits. Second, each of the patents cited is drawn to a far narrower species or subgenus than the genus encompassed by the instant claims (which encompasses essentially all catalytic antibodies). Further along, Applicants argue that there is not legal requirement to “define the specific structural features of an antibody when those of skill in the art are capable of generating any number of antibodies which can differ structurally, but all of which have the feature of binding a particular defined class of targets.” However, there is a requirement that an adequate written description of the invention be provided, and for reasons of record and as set forth above, it is maintained that the instant claims fail to meet this requirement.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-29 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record set forth in Paper No. 19, mailed 14 March 2003.

Applicants argue that “physical attachment of  $V_H$  to  $V_L$  is not required.” However, if the claim is read this way, then the grammar of the claim is still confusing, as it reads “[a]  $V_H$  and  $V_L$  polypeptide”. Under this interpretation, the claim should be drawn to a composition, collection, library, et cetera, of the two polypeptides. If a phrase were written “a 1 cent and 5 cent coin”, would the phrase be referring to a penny, a nickel, a collection of one penny and one nickel, or a single coin which is (somehow) both a penny and a nickel? As drafted, the instant claims suffer this same ambiguity of meaning.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,



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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted directly to the Examiner by facsimile transmission at (703) 746-5155. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). To send the facsimile to the Art Unit instead, the Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant does submit a paper by fax to this number, the Examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter two fax numbers unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk  
August 27, 2003



JAMES KETTER  
PRIMARY EXAMINER